REDACTED VERSION – PUBLICLY FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. MEDTRONIC VASCULAR, INC. BOSTON SCIENTIFIC CORPORATION, and SCIMED LIFE SYSTEMS, INC., Defendants.	C.A. No. 97-550-SLR (CONSOLIDATED) REDACTED VERSION – PUBLICLY FILED
BOSTON SCIENTIFIC CORPORATION, and SCIMED LIFE SYSTEMS, INC. Plaintiffs, v. ETHICON, INC., CORDIS CORPORATION, and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO. Defendants.	C.A. No. 98-19-SLR

BOSTON SCIENTIFIC'S COMBINED (I) ANSWERING BRIEF IN OPPOSITION TO CORDIS' MOTION FOR ENTRY OF FINAL JUDGMENT AND (II) OPENING BRIEF IN SUPPORT OF BOSTON SCIENTIFIC'S CROSS-MOTION TO DEFER FURTHER PROCEEDINGS AND FOR A NEW TRIAL

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June 10, 2008

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Defendants Boston Scientific Corporation and Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.) (collectively "BSC") respectfully submit this combined (i) answering brief in opposition to Cordis' motion for entry of final judgment (D.I. 1455), and (ii) opening brief in support of BSC's cross-motion to defer further proceedings and for a new trial.

INTRODUCTION

Cordis' motion for entry of final judgment without further trial proceedings is without merit, for several reasons.

First, the Federal Circuit's decisions raise new issues that require a new trial on the validity of both claims 23 and 44 of the '762 patent. A new trial on claim 23 is required because the Federal Circuit's broadened construction of the claim term "smooth surface" now includes any surface smooth enough to be intraluminally delivered. This change dramatically broadens the scope of claim 23, bringing it much closer to the prior art Ersek device, which BSC's experts have previously shown can be intraluminally delivered, and much closer to the original Palmaz woven wire stent, which Palmaz described as intraluminally deliverable, and which is described in the prior art Palmaz abstract, as well as the Palmaz monograph, which may yet be found to be prior art in the currently pending appeal of Cordis' companion case against BSC's Express stent. A new trial on the validity of claim 44 is also required because the Federal Circuit's broadened construction of the claim term "slots formed therein" now allows the formation of slots by any means instead of requiring the removal of metal. This change broadens the scope of claim 44, bringing it much closer to the prior art Ersek device and the Palmaz woven wire stent, and presents a new obviousness issue that has never been previously presented or tried. It also presents new issues of inventorship, since, to distinguish claim 44 from the prior art, Cordis will now have to rely to a much greater extent on process limitations which Stanley Carson claims to have co-invented.

Changes in claim construction which broaden the scope of a claim require a new trial on validity unless it is clear that the changes in scope were harmless and could not change the jury verdict, *i.e.*, that a jury necessarily would have reached the same result irrespective of the broadened changes in claim construction. *See Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1373-74 (Fed. Cir. 2002). Stated differently, if the record includes enough evidence to support a different verdict under the new construction, *i.e.*, enough evidence to avoid summary judgment, a new trial is mandated. *See id.* at 1374-76; *see also Cytologix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1174-76 (Fed. Cir. 2005). In this case, there is more than enough evidence already of record to support a verdict of obviousness under the Federal Circuit's newly broadened construction of claim 23, and there is no justifiable basis for summary judgment to the contrary. There is also no justifiable basis for summary judgment precluding BSC from presenting evidence on the obviousness and proper inventorship of broadened claim 44.

Second, if BSC is ultimately found liable for infringing either claim 23 or claim 44, there are a host of new issues requiring a new damages trial. For example, the recent Cordis-Medtronic arbitration result finding the AVE S-series and Driver stents to be licensed under the '762 patent makes additional non-infringing substitutes available and changes prior calculations of both lost profits and a reasonable royalty. Similarly, the Federal Circuit's change to the construction of the claim term "substantially uniform thickness" placing a maximum limitation of 100% variation on both the literal scope and the range of equivalents changes the issue of whether ACS stents are non-infringing substitutes. Finally, claim 44 is a method claim that presents several new damages issues, because BSC performs one of the claimed steps outside the United States for a significant fraction of the NIR stents sold inside the United States, thereby rendering these stents non-infringing and available as non-infringing alternatives.

Finally, Cordis' motion runs a substantial risk of wasting judicial resources if the Palmaz monograph is found to be prior art in the currently pending appeal of Cordis' companion case against the Express stent. It makes no sense for this Court to proceed with further validity proceedings before the Federal Circuit determines the scope of the prior art. If the Palmaz monograph is found to be prior art, any validity proceedings conducted by this Court in which the monograph was not considered prior art would obviously be wasted and have to be redone.

NATURE AND STAGE OF THE PROCEEDINGS

With statements such as "[t]his case is now in its second decade" and "defendants have lost repeatedly at trial and on appeal," Cordis tries to create the impression that it has secured a lopsided victory and that the entry of judgment is long overdue. Cordis' Opening Brief, D.I. 1456 ("Cordis Br.") at 1, 6-8. Cordis glosses over the fact that its case against BSC, which the Federal Circuit described as "a difficult case," has been extremely close. D.I. 1453 at 34.

Cordis originally tried this case against BSC in November 2000 on six claims of four patents (the Palmaz '762 patent, the Schatz '332 patent, and the Fischell '312 and '370 patents), after covenanting not to sue BSC on its original Palmaz '665 patent and after dropping its infringement charges under the Palmaz-Schatz '417 patent. In the first trial, the jury found all of Cordis' asserted claims either invalid or not infringed, except for one—claim 23 of the '762 patent (as amended during the *ex parte* reexamination Cordis conducted in parallel with this litigation), and the jury found that claim infringed only under the doctrine of equivalents and not literally. D.I. 182 (C.A. No. 98-197) (Ex. A) at 2-8.

The verdict that claim 23 was infringed by equivalents was later set aside, because this Court ruled that equivalents for at least one claim term, "substantially uniform thickness," should have been limited by prosecution history estoppel, and the lack of a detailed verdict form made it impossible to tell whether the jury's equivalents verdict was based on a legally impermissible

finding of equivalents for this term. D.I. 1153 at 3-4. The Court did not rule at that time upon BSC's other prosecution history estoppel arguments, including the argument that the claim term "smooth surface" was limited by amendment-based estoppel and should have been accorded no equivalents under *Festo*. D.I. 1127 at 38 n. 16.

The BSC case was then stayed pending the outcome of a separate appeal of Cordis' case against Medtronic AVE. D.I. 1153 at 9-10. BSC was not a party to the AVE appeal, but the Federal Circuit's ruling in that appeal overturning the specific prosecution history estoppel found by this Court for "substantially uniform thickness," and broadening the literal scope of that term but limiting the range of equivalents, changed the issues thereby requiring the second BSC trial. In that trial, Cordis dropped its equivalents argument and argued only that the claim term "substantially uniform thickness" was infringed literally under the new construction. The infringement issues in the second BSC trial were thus artificially limited to the question of whether this limitation was literally infringed, and BSC was precluded from referring to whether any of the other limitations had been found infringed literally or only by equivalents in the prior verdict.

The jury returned a verdict of infringement in the second trial based only on its findings with respect to "substantially uniform thickness." D.I. 1366 (Ex. B) at 2. This Court then entered judgment against BSC based on the combined verdicts of the two trials. D.I. 1432.

BSC appealed this composite infringement verdict on grounds including, *inter alia*, the failure of this Court to find that the claim term "smooth surface" was limited by prosecution history estoppel under *Festo*, thereby requiring a new trial on infringement for the same reasons as this Court's original new trial ruling, namely, that the lack of a detailed verdict form in the first trial made it impossible to tell whether the original equivalents verdict was based on a

legally impermissible finding of equivalents. The Federal Circuit side-stepped the prosecution history estoppel issue regarding "smooth surface," and instead upheld the infringement verdict by broadening the literal construction of the "smooth surface" limitation to include any surface smooth enough to be intraluminally delivered, even though upholding the infringement verdict on this ground had the effect of reopening validity issues for claim 23. D.I. 1453 at 31-34.

Cordis cross-appealed the judgment from the first BSC trial holding claim 44 invalid under 35 U.S.C. § 305. The Federal Circuit ruled in favor of Cordis on this cross-appeal, thereby re-injecting claim 44 into the case for further proceedings. D.I. 1453 at 41-44.[1]

Thus, now that BSC has had its first and only appeal, the case has now been remanded for this Court to consider further proceedings in light of the Federal Circuit's broadening changes in claim construction for the claim terms "smooth surface" and "slots formed therein." D.I. 1453 at 34; D.I. 1454 at 3.

ARGUMENT

I. Further Proceedings in this NIR Case Should Be Deferred at Least Until the Pending Appeal in the Express Case Is Over

The Court should deny Cordis' motion for the entry of final judgment against BSC, including Cordis' request for damages and interest. Instead, the more efficient and prudent course of action would be for the Court to defer further proceedings on the liability and damages issues. Specifically, the Court should defer further proceedings on validity until early next year after the Federal Circuit decides whether or not the Palmaz monograph is prior art in the pending appeal in Cordis' companion case against BSC's Express stent. If the Court ultimately enters

[1] In its initial opinion, the Federal Circuit apparently failed to recognize that its earlier decision in the first Cordis-AVE appeal broadening the claim term "slots formed therein" would reopen validity issues for claim 44. D.I. 1453. However, the Federal Circuit instructed this Court to consider the issue in its order responding to BSC's petition for rehearing. D.I. 1454 at 3.

judgment that BSC is liable for infringement, it should also defer further proceedings on damages issues until after all of the liability issues have been finally determined through appeal.

A. Further Proceedings on the Liability Issues Should Be Deferred Until the Prior Art Status of the Palmaz Monograph is Decided by the Federal Circuit in the Pending Appeal in the Express Case

The Federal Circuit instructed this Court on remand to determine whether further proceedings on the validity of claims 23 and 44 are warranted in view of the Federal Circuit's modified constructions of the claim terms "smooth surface" in claim 23 and "slots formed therein" in claim 44. D.I. 1453 at 34; D.I. 1454 at 3. As explained below, a new invalidity trial is necessary because the modified constructions broadened the claim scope and made the claimed subject matter closer to the prior art, including the fixation sleeve disclosed in the Ersek patent,[2] the balloon-expandable stent disclosed in the Palmaz abstract,[3] and—if it qualifies as prior art—the balloon-expandable stents disclosed in the Palmaz monograph.[4]

However, further proceedings on validity, including a new trial, should be deferred at least until early next year after the Federal Circuit decides the pending appeal in Cordis' companion case against BSC's Express stent. In that appeal, the Federal Circuit will review *de novo* this Court's summary judgment decision in the Express case that the Palmaz monograph is not a prior art "printed publication" under 35 U.S.C. § 102(b). D.I. 338 (C.A. No. 03-027) (Ex. G) at 8-12; *see Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1377 (Fed. Cir. 2006) (whether a reference is a "printed publication" under 35 U.S.C. § 102(b) is a question of law

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[2] The "Ersek patent" refers to prior art U.S. Patent No. 3,657,744 to Ersek, DX-15004 (Ex. C).

[3] The "Palmaz abstract" refers to the prior art abstract published in advance of Dr. Palmaz's presentation at the 1984 Annual Meeting of the Radiological Society of North America, DXB-15006 (Ex. D).

[4] The "Palmaz monograph" refers to the article prepared in 1980 by Dr. Palmaz which discloses his balloon-expandable woven-wire and slotted-tube stents, PX-652 (Ex. E), as well as the revised version of that article prepared in 1983, PX-1557 (Ex. F).

subject to *de novo* review). If the Federal Circuit decides that the Palmaz monograph is prior art, then any further proceedings on the validity of claims 23 and 44 in this case against the NIR stent clearly should take that finding into account. Cordis cannot seriously dispute that the Palmaz monograph anticipates (or at the very least renders obvious) the claimed subject matter.[5]

It would waste judicial resources to conduct further proceedings on validity issues before the Federal Circuit decides the potentially dispositive issue of whether the Palmaz monograph is prior art. Therefore, the Court should exercise its discretion to defer further proceedings at least until early next year after the Federal Circuit issues its mandate in the appeal in the Express case.[6] *See In re Itron, Inc.*, 31 Fed. Appx. 664, 665 (Fed. Cir. 2002) (no abuse of discretion in waiting for an appellate decision in a separate patent case that would potentially impact the instant case); *see also Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936) ("[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.").

B. Further Proceedings on Damages Issues Should Be Deferred Until All Liability Issues Are Finally Determined Through Appeal

The Court should also adhere to its prior ruling to defer further proceedings on damages issues. Both before and after the liability trial in 2005, the Court bifurcated and deferred the damages issues until after the liability issues had been finally determined through appeal. *See* D.I. 1253 (Ex. I) at 27; D.I. 1435 at 4-6. As the Court explained, "it is prudent to address the

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[5] Indeed, the Patent Office has recently rejected both claim 23 and claim 44 as being anticipated by the Palmaz monograph in the currently pending reexamination of the '762 patent. *See* 5/7/08 Office Action In Reexamination No. 90/007,627 (Ex. H). This reexamination is an additional reason why the Court should defer further proceedings. *See Alloc, Inc. v. Unilin Décor N.V.*, No. 03-253-GMS, 2003 U.S. Dist. LEXIS 11917, at *9 (D. Del. July 11, 2003) (granting stay pending reexamination).

[6] BSC filed its principal appeal brief in the Express case on May 12, 2008, and expects the appeal to be briefed and argued by the end of 2008, with a decision by the Federal Circuit in early 2009.

damages issues only after the liability issues have been finally resolved through appeal, so as to prevent any further delay in the ultimate resolution of this litigation." D.I. 1435 at 4. The Court should adhere to this ruling now for the same reason. It would waste judicial resources to conduct further damages proceedings that may turn out to be unnecessary if the claims are found invalid. *See, e.g., Kaufman Co. v. Lantech, Inc.*, 926 F.2d 1136 (Fed. Cir. 1991) (damages trial did not commence until after Federal Circuit affirmed lower court's liability judgment).

II. A New Invalidity Trial Is Required for Both Claims 23 and 44 Because the Federal Circuit Broadened the Construction of Critical Claim Terms

A new invalidity trial is required for both claims 23 and 44 because of the broadened claim scope arising from the Federal Circuit's modified constructions of the claim terms "smooth surface" and "slots formed therein." Thus, if the Court elects not to defer further proceedings as requested above, Cordis' motion for entry of final judgment should still be denied.

A. A Changed Claim Construction that Broadens the Claim Scope Warrants a New Invalidity Trial Unless the Jury Necessarily Would Have Reached the Same Result

The validity of a patent claim in view of the prior art under 35 U.S.C. §§ 102 and 103 depends on the differences, if any, between the claimed subject matter and the prior art. *See, e.g., Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). Therefore, a key step in the validity analysis is to compare the claim scope to the prior art to identify any differences. *Id.* However, this comparison can take place only after the claim scope has been defined by construing the claim language. *See TI Group Auto. Sys. (N. Am.), Inc. v. VDO N. Am., LLC*, 375 F.3d 1126, 1139 (Fed. Cir. 2004) ("Our validity analysis is a two-step procedure: 'The first step involves the proper interpretation of the claims. The second step involves determining whether the limitations of the claims as properly interpreted are met by the prior art.'" (quotation omitted)).

Since the validity analysis depends on the differences between the claim scope and the prior art, which in turn depend on claim construction, the broadening of a construction on appeal changes the validity analysis by changing the comparison of the claim scope to the prior art. *See TI Group*, 375 F.3d at 1139-40 (vacating and remanding for further proceedings since broadened construction "affect[ed] the invalidity analysis" because "the jury could only have compared the prior art to the erroneously narrowly construed claims"); *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1179 (Fed. Cir. 2002) (vacating and remanding for further validity proceedings because judgment was "based upon an incorrect construction").

Similarly, whether a claim is invalid for improper inventorship also depends on its scope, which in turn depends on claim construction. A key step in an inventorship analysis is to compare the claimed subject matter to the contributions of each co-inventor. *See Trovan, Ltd. v. Sokymat SA*, 299 F.3d 1292, 1302 (Fed. Cir. 2002). This comparison can take place only after the claim scope has been defined by construing the claim language. *Id.* ("[A]n inventorship analysis, like an infringement or invalidity analysis, begins as a first step with a construction of each asserted claim to determine the subject matter encompassed thereby. The second step is then to compare the alleged contributions of each asserted co-inventor with the subject matter of the properly construed claim to then determine whether the correct inventors were named." (citations omitted)). Thus, the modification of a claim construction on appeal changes the claim scope and the inventorship analysis. *See id.* at 1309 n.2 (vacating inventorship findings and remanding for "further factual development in light of the proper claim construction").

As with any legal error in a jury instruction, "[a]n erroneous instruction regarding claim interpretation that affects the jury's decision . . . is grounds for a new trial." *Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1373 (Fed. Cir. 2002). Specifically, a claim construction error

is prejudicial and warrants a new trial unless it was harmless. *Id.* at 1374. An error is harmless only if it "could not have changed the result." *Id.* In other words, "the evidence in support of the verdict" must be "so overwhelming that the same verdict would necessarily be reached absent the error." *Id.* (quoting *Weinar v. Rollform, Inc.*, 744 F.2d 797, 808 (Fed. Cir. 1984)). Stated differently, a claim construction error is prejudicial and warrants a new trial if sufficient evidence was proffered below to support a different verdict under the correct construction. *See Ecolab*, 285 F.3d at 1374-76 (vacating noninfringement judgment and remanding for new trial on ground that claim construction error was prejudicial "[b]ecause we find sufficient evidence to support a jury verdict of infringement under the correct interpretation"); *see also Cytologix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1174-76 (Fed. Cir. 2005) (vacating validity judgment and remanding "for the district court to consider a new trial on the issue of obviousness under the correct claim construction" because the defendant's evidence "may have constituted substantial evidence that would support a jury verdict of obviousness under the correct claim construction").

Thus, if a verdict that a claim is valid over the prior art was reached under an unduly narrow claim construction that is broadened on appeal, a new validity trial is necessary unless the jury necessarily would have reached the same result under the broader construction. *See Ecolab*, 285 F.3d at 1373-76; *see also Cytologix*, 424 F.3d at 1174-76.[7] Since an inventorship analysis

[7] Consistent with this precedent, the Court has on three separate occasions—including in this case—ordered a new invalidity trial on remand after the Federal Circuit broadened a claim construction. *See* D.I. 1295 at 6 (denying summary judgment and allowing new obviousness trial for claim 23 to proceed on remand from first Cordis-AVE appeal because Federal Circuit broadened construction of "slots formed therein" limitation); *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 270 F. Supp. 2d 519, 523 (D. Del. 2003) (Robinson C.J.) (ordering new obviousness trial on remand after Federal Circuit broadened claim construction); *TA Instruments, Inc. v. Perkin-Elmer Corp.*, No. 95-545-SLR, 2002 U.S. Dist. LEXIS 5959, at *7 (D. Del. Mar. 28, 2002) (Robinson C.J.) (defendant entitled to assert prior art invalidity defense on remand "because of the Federal Circuit's revised claim construction").

also depends on claim construction, the same analysis should apply in determining whether a modified construction warrants a new inventorship trial. *Cf. Trovan*, 299 F.3d at 1309 n.2.

This precedent compels the conclusion that the Federal Circuit's broadened constructions of "smooth surface" and "slots formed therein" require a new invalidity trial for claims 23 and 44 (after the appeal in the Express case is over). As explained below, the jury would not necessarily have reached the same result under these broadened constructions. On the contrary, BSC proffered sufficient evidence to support an invalidity verdict under the changed constructions.

The harmless error cases cited by Cordis do not compel a different conclusion. Cordis Br. at 8-11.

In *Teleflex v. Ficosa North America Corp.*, 299 F.3d 1313 (Fed. Cir. 2002), "the evidence supporting validity remain[ed] unaffected by [the Federal Circuit's] correction of the district court's [unduly narrow] claim construction" because there was no substantial evidence of a motivation to combine even under the modified construction. *Id.* at 1334 ("Evidence introduced at trial . . . showed a lack of motivation to combine a serviceable connector with any clip, regardless of the presence of a 'single pair of legs.'" (citing *Ecolab*, 285 F.3d at 1374; *Weinar*, 744 F.2d at 808)). In contrast, as explained below, BSC proffered more than sufficient evidence of obviousness and improper inventorship to support invalidity verdicts for claims 23 and 44 under the broadened constructions of "smooth surface" and "slots formed therein."

In *Eaton Corp. v. Rockwell International Corp.* 323 F.3d 1332, 1344 (Fed. Cir. 2003), the Federal Circuit held that the narrowing of an unduly broad construction did not warrant a new invalidity trial because the "narrower claim construction [did not] make it easier for [the defendant] to establish invalidity at a new trial." In contrast, here the constructions of "smooth

surface" and "slots formed therein" were broadened on appeal, which, as explained below, makes it easier for BSC to prove invalidity.

In *Finisar Corp. v. DirectTV Group, Inc.*, 523 F.3d 1323 (Fed. Cir. 2008), the Federal Circuit held that an unduly broad construction was harmless error because the difference between the proper and erroneous constructions depended on the specificity of another term, the construction of which the defendant had not appealed. *Id.* at 1333.

Finally, in *Lucent Technologies, Inc. v. Newbridge Networks Corp.*, 168 F. Supp. 2d 181, 254-55 (D. Del. 2001), the Court held that a claim construction error did not warrant a new trial because the defendant conceded it did not "undermine[] in any way [the plaintiff's] infringement case." In contrast, here the changed constructions do undermine Cordis' validity case.[8]

B. A New Invalidity Trial Is Warranted for Claim 23 Because the Changed Construction of "Smooth Surface" Broadens the Claim Scope and Makes It Closer to the Prior Art

The change from the prior narrow, structural construction of "smooth surface" to the Federal Circuit's new broad, functional construction is not harmless and warrants a new invalidity trial for claim 23. As explained below, the jury would not necessarily have concluded that claim 23 is valid under the new construction, because the change broadens the scope of the claim and makes the claimed subject matter closer to the prior art.

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[8] The other cases cited by Cordis do not undermine BSC's arguments. Several cases did not relate to an erroneous jury instruction. *See Mcdonough Power Equip., Inc. v. Greenwood*, 464 U.S. 548, 549 (1983) (error during jury *voir dire*); *Ivy v. Mansfield*, No. 2007-7171, 2007 WL 4105280, at *2 (Fed. Cir. Nov. 19, 2007) (unpublished) (failure to comply with notice requirements of Veterans Claims Assistance Act); *General Motors Corp. v. New A.C. Chevrolet, Inc.*, 263 F.3d 296, 329 (3d Cir. 2001) (erroneous dismissal of counterclaim). Although the remaining cases addressed erroneous instructions, they did not address an erroneous claim construction. *See Environ Prods., Inc. v. Furon Co.*, 215 F.3d 1261, 1265 (Fed. Cir. 2000) (instruction regarding burden of proof for inventorship); *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 852-53 (Fed. Cir. 2006) (instruction regarding adverse inference on willfulness due to assertion of attorney-client privilege); *True N. Composites, LLC v. Trinity Indus., Inc.*, 191 F. Supp. 2d 484, 517-18 (D. Del. 2002) (instruction on implied duty of good faith and fair dealing in contract law).

1. Cordis Relied on the Narrow, Structural Construction of "Smooth Surface" at Trial To Distinguish the Prior Art

At the second trial in 2005, the jury evaluated the validity of claim 23 under the prior construction of "smooth surface," which required the outer surface of the unexpanded "tubular member" to be "continuously even" and "without roughness, points, bumps or ridges, especially to the touch." D.I. 1127 at 9; D.I. 1373, 3/23/05 Tr. (Ex. J) at 1352. Cordis relied on this narrow, structural construction at trial in defending against BSC's invalidity challenge, by arguing that the prior art devices on which BSC relied did not have a smooth outer surface without bumps. Specifically, Cordis asserted that the Ersek sleeve had bumps at the bridges and that the woven-wire stent of the Palmaz abstract had bumps at the soldered cross-over points.

For example, Nigel Buller, Cordis' cardiology expert, testified that the surface of the Ersek sleeve "is the antithesis of smooth" because it "has a multitude of outwardly projecting edges," which render it "rough, sharp and certainly not smooth." D.I. 1370, 3/18/05 Tr. (Ex. K) at 504, 507. He also testified that the surface of the woven-wire stent of the Palmaz abstract is not smooth because of the bumps at the cross-over points. *Id.* at 523, 538. Cordis further emphasized these distinctions during its closing argument, stressing that Ersek and the Palmaz woven-wire stent did not have a smooth surface. D.I. 1373, 3/23/05 Tr. (Ex. J) at 1305, 1326.

In response, Alan Snyder, BSC's biomedical engineering expert, testified that although the bumpy outer surfaces of Ersek and the woven-wire stent are not "smooth" under the Court's prior construction, one of ordinary skill would have been motivated to eliminate these bumps in order to arrive at the claimed "smooth surface." D.I. 1372, 3/22/05 Tr. (Ex. L) at 947-51.

Having relied on this narrow, structural construction of "smooth surface" to distinguish the prior art at trial, Cordis did an about-face on appeal. It urged a broad, functional construction to preserve its infringement claim against BSC's NIR stent, which, like the prior art, has a

bumpy outer surface due to its protruding U-loops and welds. Specifically, Cordis argued that the Federal Circuit did not need to reach BSC's prosecution history estoppel arguments addressing the range of equivalents for the "smooth surface" limitation because the NIR stent literally meets this limitation under Cordis' proposed construction, which merely requires the surface to be smooth enough to intraluminally deliver. Cordis App. Br. at 56-57 (Ex. M). The Federal Circuit adopted Cordis' construction, but it instructed this Court to determine on remand "[w]hether, on the facts of this case, the broader definition requires any further proceeding with respect to the issue of obviousness." D.I. 1453 at 34.

2. The Change to the Construction of "Smooth Surface" Is Not Harmless Because the Jury Could Have Reached a Different Result

The change from the prior narrow, structural construction of "smooth surface" to the Federal Circuit's broad, functional construction is not harmless and warrants a new invalidity trial for claim 23. The changed construction broadened the claim scope and made it closer to the prior art, which changed the invalidity analysis by changing the comparison to the prior art under 35 U.S.C. §§ 102 and 103. *See TI Group*, 375 F.3d at 1139-40; *Union Carbide*, 308 F.3d at 1179. The jury would not necessarily have reached the same result under the modified construction, because BSC no longer needs to prove that the prior art discloses a graft with a "smooth surface" without bumps, or that there was a motivation to modify it to make it smooth in this sense. Instead, BSC merely needs to prove that the prior art discloses a graft that is smooth enough to deliver, or that there was a motivation to make the graft deliverable.[9]

[9] It will also be easier for BSC to meet its burden of proving the existence of such a motivation in a new trial than in the trial in 2005 because of the more flexible obviousness standard mandated by the Supreme Court in its intervening decision in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007).

This difference is significant given the evidence. Even with the bumps at the soldered cross-points, the Palmaz abstract discloses a woven-wire "expandable intraluminal graft" that is smooth enough to intraluminally deliver. DXB-15006 (Ex. D). Moreover, BSC also presented evidence that, even with the bumps at the bridges, the Ersek sleeve would have been smooth enough to intraluminally deliver, and that even if it were not, there was a motivation to make it deliverable. As Dr. Snyder explained, the Ersek patent teaches that "the edges [of the sleeve] may be cuffed if desired or simply smoothed to facilitate entry." D.I. 1372, 3/22/05 Tr. (Ex. L) at 950 (citing DX-15004 (Ex. C), col. 3, ll. 13-14). Moreover, he explained that one of ordinary skill would have been motivated to make Ersek deliverable because of the general knowledge about balloon angioplasty and the teaching about intraluminal delivery of the woven-wire stent in the Palmaz abstract. D.I. 1372, 3/22/05 Tr. (Ex. L) at 950-57. Dr. Snyder and BSC's cardiology expert, Reginald Low, experimentally confirmed that an Ersek device would have been smooth enough to intraluminally deliver by delivering and expanding expanded-metal stents on balloon catheters in the coronary arteries of a pig, without causing damage to the arteries or the balloons. D.I. 1372, 3/22/05 Tr. (Ex. L) at 925-928, 1083-98; *see also id.* at 913-24; DXB-15276 (Ex. N); DXB-15280 (Ex. O); DXB-15010 to DXB-15017 (Ex. P). Thus, BSC presented more than sufficient evidence to support an invalidity verdict for claim 23 under the broadened construction.

The broadened construction of "smooth surface" also makes the subject matter of claim 23 closer to the Palmaz monograph. Cordis asserts that the 1980 version of the monograph discloses only the woven-wire embodiment, not the slotted-tube embodiment. *See* Rebuttal Expert Report of Nigel Buller (C.A. No. 03-027) (Ex. Q) at 21-22; 3/2/05 Buller Dep. Tr. (Ex. R) at 263-70. Under the prior construction, Cordis asserted that the woven-wire stent did not

disclose a "smooth surface" because of the bumps at the cross-over points. D.I. 1370, 3/18/05 Tr. (Ex. K) at 523. Under the broadened construction, which merely requires the stent to be smooth enough to intraluminally deliver, Cordis can no longer make this distinction, because the monograph clearly discloses intraluminal delivery. PX-652 (Ex. E) at TH11710; 3/2/05 Buller Dep. Tr. (Ex. R) at 263-70. In sum, if the Palmaz monograph is prior art, it constitutes more than sufficient evidence to support an invalidity verdict for claim 23 under the new construction.

Given the impact of the broadened construction of "smooth surface" on the invalidity issues, the jury would not necessarily have reached the same result under the new construction. Therefore, the changed construction is not harmless and warrants a new trial.

3. Cordis' Harmless Error Analysis Is Flawed Because It Assumes Incorrectly that BSC Has Already Lost a Trial On Whether the Prior Art Taught Intraluminal Delivery

Cordis tries to avoid the need for a new invalidity trial for claim 23 by arguing that the jury "would have reached the same result" under the broadened construction of "smooth surface" because "BSC has already tried – and lost – a case on whether it was obvious to modify Ersek to make it smooth enough for intraluminal delivery." Cordis Br. at 22, 11; *see also id.* at 11-22.[10]

Cordis has no basis for this assertion. Although the jury concluded that claim 23 was not obvious, it is not possible to determine which claim limitations the jury concluded were not taught or rendered obvious by the prior art. The jury may have agreed with BSC that the Ersek sleeve can be intraluminally delivered, especially in light of BSC's experts' experimental evidence to this effect. D.I. 1372, 3/22/05 Tr. (Ex. L) at 925-928, 1083-98; *see also id.* at 913-

[10] *See also* Cordis Br. at 13 ("BSC then litigated the functional question of whether it would have been obvious to modify the Ersek device to make it suitable for intraluminal delivery – and it lost."); *id.* at 21 ("BSC has already had one trial on the functional issue of whether it would have been obvious in 1985 to modify the Ersek device to make it smooth enough for intraluminal delivery – and it lost.").

24; DXB-15276 (Ex. N); DXB-15280 (Ex. O); DXB-15010 to DXB-15017 (Ex. P). However, the jury may have disagreed with BSC that there was a motivation to go beyond this and modify Ersek's outer surface to arrive at the claimed invention by making it "smooth" under the prior construction, which required the surface to be "continuously even . . . without roughness, points, bumps or ridges."[11]

To borrow Cordis' phraseology, it may be the case only that "BSC has already tried – and lost – a case on whether it was obvious to modify Ersek to make it 'continuously even' and 'without roughness, points, bumps or ridges,'" which, of course, is something that BSC no longer needs to prove under the broadened construction. BSC may in fact have already won "a case on whether it was obvious to modify Ersek to make it smooth enough for intraluminal delivery." It is not possible to determine which feature(s) the jury found not to be obvious—and Cordis has no basis to contend otherwise.[12]

Similarly, Cordis is incorrect when it asserts that "[t]he case that BSC presented in the 2005 re-trial based on the original construction of 'smooth' is no different than the case it would present now, after the definition of 'smooth' has been revised to mean smooth enough for intraluminal delivery." Cordis Br. at 16. As explained above, under the new construction, BSC

[11] Cordis incorrectly asserts (without citation) that the expanded metal stents that BSC's experts successfully intraluminally delivered and expanded in the pig "met every limitation of the earlier claim construction," including the "smooth surface" limitation. Cordis Br. at 17. BSC's expert actually testified that the device "does have bumps and ridges" and that "[he] would not say that this really has a smooth surface," but that it would have been obvious to modify it to make it smooth in this sense. D.I. 1372, 3/22/05 Tr. (Ex. L) at 947-57; *see also* DX-15016 to DX-15017 (Ex P). Cordis' expert apparently did not address this issue at trial, but in his deposition he testified that these devices were not "smooth" under the prior construction. 9/10/04 Buller Dep. Tr. at 272-75 (Ex. S).

[12] Specifically, Cordis has no basis to assert that "BSC did not, and could not, show that one of ordinary skill in 1985 would have had any reason to flatten the outwardly projecting edges of the Ersek device to make it suitable for intraluminal delivery." Cordis Br. at 18. Indeed, the jury may have agreed with BSC on this issue but upheld the validity of claim 23 anyway by concluding that it would not have been

no longer needs to prove—and the jury no longer needs to find—that the prior art discloses a graft with a "smooth surface" without bumps, or that there was a motivation to modify it to make it smooth in this sense. Instead, BSC merely needs to prove that the prior art discloses a graft that is smooth enough to deliver, or a motivation to make it deliverable. Thus, the jury would not necessarily have reached the same verdict under the broadened construction.

4. Cordis' Attempt To Downplay the Significance of the Changed Construction of "Smooth Surface" Is Inconsistent with the Critical Importance of this Limitation to Patentability and Infringement

Cordis also argues that the changed construction of "smooth surface" is harmless by incorrectly asserting that "[t]he difference between [the prior construction and the new construction] – if there is one – is virtually imperceptible" and is "very minor." Cordis Br. at 21; *id.* at 13. According to Cordis, "[a] stent that is smooth under the original construction – smooth to the touch – is smooth enough for intraluminal delivery, and a stent that is smooth enough for intraluminal delivery is also smooth in any ordinary use of language." *Id.* at 21. Cordis' attempt to downplay the differences between the prior and new constructions should be rejected.

First, the Federal Circuit has already concluded that the new construction is a "broader definition" than the prior construction. D.I. 1453 at 34. This legal claim construction ruling is part of the appellate mandate that is binding on remand. *See AFG Indus., Inc. v. Cardinal IG Co.*, 375 F.3d 1367, 1372 (Fed. Cir. 2004).

Second, Cordis is able to downplay the significance of the changed construction only by glossing over what the prior construction actually required. Cordis paraphrases the construction as though it merely required the surface to be "smooth to the touch," but it actually required the

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obvious to go beyond this and flatten Ersek to make the outer surface "continuously even" and "without roughness, points, bumps or ridges."

surface to be "continuously even" and "without roughness, points, bumps or ridges, especially to the touch." D.I. 1127 at 9. Cordis does not, and cannot, argue that a stent that is smooth enough to intraluminally deliver also necessarily has a "continuously even" surface "without roughness, points, bumps or ridges." Indeed, Dr. Palmaz's own woven-wire embodiment is smooth enough to intraluminally deliver without having a "continuously even" surface "without . . . bumps or ridges" at the cross-over points. Moreover, the fact that BSC's NIR stent is smooth enough to deliver and therefore literally has a "smooth surface" under the new construction, but that the jury concluded it did not literally infringe claim 23 under the prior construction, illustrates the significance of the changed construction. D.I. 1453 at 31-34; D.I. 182 (C.A. No. 98-197) (Ex. A) at 2-3.

Third, Cordis' argument is also inconsistent with the critical importance of its structural distinction of Ersek's bumpy surface to the Patent Office's decision to confirm the patentability of claim 23. After the examiner had rejected both independent claim 13 and dependent claim 23 as being anticipated by the structure of the Ersek sleeve, Cordis cancelled claim 13 (which does not contain the "smooth surface" limitation) and argued that Ersek did not have the "smooth surface" required by claim 23 because of its "outwardly projecting edges." PX-13 (Ex. T) at 3015-17, 3039, 3049-50, 3055, 3057; PX-14 (Ex. U) at 3243-46. The examiner accepted this structural distinction as the basis for concluding that claim 23 was patentable, stating that "[u]pon reconsideration, the outside of the wall surface of the Ersek (3,657,744) fixation sleeve is not considered to be smooth" because it "includes a multitude" of "abrupt obstacle[s] at [each] bridge (at the junction of the strands)," "making [the outer surface of the sleeve] rough rather than smooth." PX-14 (Ex. U) at 3257-58.

In sum, it is disingenuous for Cordis to trivialize the significance of the "smooth surface" limitation when it was so critical to patentability and to the infringement issues in this case.

C. A New Invalidity Trial Is Warranted for Claim 44 Because the Changed Construction of "Slots Formed Therein" Broadens the Claim Scope and Makes It Closer to the Prior Art and to Dr. Carson's Inventive Contribution

The change from the prior strict construction of "slots formed therein" to the Federal Circuit's new broad construction is not harmless and warrants a new invalidity trial for claim 44. As explained below, the jury would not necessarily have concluded that claim 44 is valid under the new construction, because the change broadened the claim scope and made it closer to the prior art and to the contribution of an unnamed co-inventor, Stanley Carson.

1. The Broadened Scope of Claim 44 Changes the Comparison of the Claimed Subject Matter To the Prior Art

a. The Court Has Already Ruled that the Changed Construction of "Slots Formed Therein" Warrants a New Invalidity Trial

Prior to the trial in 2000, the Court construed the claim term "slots formed therein" to "require[] that the slots be manufactured by removing material from a pre-existing wall surface." D.I. 1171 at 7-8; *see also* D.I. 790 at 3. After trial, in the first Cordis-AVE appeal, the Federal Circuit reversed this ruling, holding that "[s]lots can be 'formed' in a wall surface by means other than removing material, such as by constructing the wall with openings built into it." D.I. 1171 at 8.

On remand, the Court correctly held that the modified construction of "slots formed therein" warranted a new invalidity trial for claim 23 because it broadened the claim scope and changed the invalidity analysis. D.I. 1295 at 4 ("The consideration of obviousness changed as a result of the revised claim construction." (citing *TI Group*, 375 F.3d at 1139-40)).

The Court's reasoning applied with equal force to claim 44, which also contains the "slots formed therein" limitation. However, at the time claim 44 had already been adjudicated to

be invalid under 35 U.S.C. § 305. D.I. 1127 at 51-56; D.I. 182 (C.A. No. 98-197) (Ex. A) at 6. Thus, the issue of whether claim 44 was invalid over the prior art was moot and not justiciable, and the parties agreed before the trial in 2005 that this issue should not be tried. *See* D.I. 1287-5 (Ex. V); D.I. 1299-5 (Ex. W).

Now that the Federal Circuit has reversed the decision that claim 44 is invalid under section 305, a new invalidity trial for that claim is warranted under the new construction of "slots formed therein." As the Court previously held with respect to claim 23, the changed construction changed the validity analysis. *See* D.I. 1295 at 4.

b. The Change In the Construction Of "Slots Formed Therein" Is Not Harmless Because the Jury Could Have Reached a Different Result

The change from the prior narrow construction of "slots formed therein" to the Federal Circuit's broad construction broadens the claim scope and makes it closer to the prior art, thereby changing the invalidity analysis by changing the comparison to the prior art. *See TI Group*, 375 F.3d at 1139-40; *Union Carbide*, 308 F.3d at 1179. The jury would not necessarily have concluded that claim 44 is valid under the broadened construction, because BSC no longer needs to prove that the prior art disclosed a graft with openings formed by removing material from a preexisting wall, or that there was a motivation to remove material. Instead, BSC merely needs to prove that the prior art disclosed a graft with openings ("slots") in its wall.

This difference is significant. Under the original construction, both Ersek and the Palmaz abstract did not disclose "slots formed therein" because they disclose devices with openings that are not formed by removing material from a preexisting wall. The openings in the Ersek sleeve are formed by cutting slits in a metal sheet and stretching the sheet to pull the openings apart. DX-15004 (Ex. C), col., 2, l. 56 to col. 3, l. 19, Fig. 2. The openings in the Palmaz woven-wire stent are formed by weaving wire into a mesh. DXB-15006 (Ex. D). Under the new

construction, which no longer requires material to be removed, both of these prior art grafts now have "slots formed therein." Therefore, BSC no longer needs to prove that one of ordinary skill would have been motivated to modify the prior art to arrive at this feature.

Moreover, BSC presented more than sufficient evidence to support an invalidity verdict for claim 44 under the broadened construction. As explained above, BSC's experts experimentally confirmed that an expanded metal Ersek stent can be crimped on a balloon catheter, intraluminally delivered on the catheter to a coronary artery, expanded by the balloon, and implanted in the artery. D.I. 1372, 3/22/05 Tr. (Ex. L) at 925-928, 1083-98; *see also id.* at 913-24; DXB-15276 (Ex. N); DXB-15280 (Ex. O); DXB-15010 to DXB-15017 (Ex. P).

The broadened construction of "slots formed therein" also makes the subject matter of claim 44 closer to the Palmaz monograph. As noted above, Cordis asserts that the 1980 version of the monograph discloses only the woven-wire embodiment. Under the prior construction, the woven-wire stent did not have "slots formed therein" because no material is removed from a preexisting wall to form the openings. Under the broadened construction, which does not require material to be removed, Cordis can no longer make this distinction. Therefore, if the Palmaz monograph is prior art, it constitutes more than sufficient evidence to support an invalidity verdict for claim 44 under the broadened construction.

Given the impact of the broadened construction of "slots formed therein" on the invalidity issues, the jury would not necessarily have concluded that claim 44 is valid under the new construction. Therefore, the changed construction is not harmless and warrants a new trial.

c. BSC Did Not Concede that Claim 44 Is Valid

Cordis argues that the changed construction of "slots formed therein" is harmless because "during the re-trial [of claim 23 in 2005] under the revised claim construction of 'slots formed therein,' BSC conceded the nonobviousness of the claim 44 method." Cordis Br. at 24.

This assertion is unfounded. BSC has never admitted that claim 44 is valid under 35 U.S.C. §§ 102 or 103. The statements by BSC's counsel during the trial in 2005 to which Cordis refers did not specifically address claim 44, much less whether that claim is valid under 35 U.S.C. §§ 102 or 103. *Id.* at 26-29. The trial addressed only one claim—claim 23. Claim 44 was not at issue at trial because it had already been adjudicated to be invalid under section 305.

When read in context, it is clear that BSC was merely responding to Cordis' arguments that claim 23 was not obvious because of evidence of secondary considerations of nonobviousness, such as praise, recognition and success. *See* D.I. 1371, 3/21/05 Tr. (Ex. X) at 704, 706-07. Specifically, BSC argued there was no nexus between this evidence and the apparatus of claim 23 because this evidence did not relate to the stent itself. *See* D.I. 1369, 3/17/05 Tr. (Ex. Y) at 126-28, 133; D.I. 1373, 3/23/05 Tr. (Ex. J) at 1241, 1242-43, 1265-66. BSC was also responding to Cordis' argument that claim 23 was not obvious because Ersek is used in a different application. *See* D.I. 1370, 3/18/05 Tr. (Ex. K) at 468-69, 492-500; D.I. 1373, 3/23/05 Tr. (Ex. J) at 1319, 1321. BSC argued that this different use did not matter because claim 23 is an apparatus claim, not a method claim, and therefore its patentability depends on its structure, not how it is used. *See* D.I. 1373, 3/23/05 Tr. (Ex. J) at 1245-46. In sum, none of BSC's statements addressed claim 44, much less constituted an admission that it is valid.

d. BSC Did Not Waive a New Invalidity Trial for Claim 44

Cordis again tries to argue that BSC waived a new invalidity trial for claim 44 by not seeking to try the validity of claim 44 at either of the prior trials. Cordis Br. at 25-27.

This argument should be rejected.

The Court previously ruled that BSC did not waive a new trial by not trying validity under the prior construction at the first trial in 2000. Cordis made the same waiver argument that it now makes on remand from the first Cordis-AVE appeal. *See* D.I. 1259 (Ex. Z) at 18-23; D.I.

1280 (Ex. AA) at 12-13. At that time, the Court correctly rejected Cordis' waiver argument and held that the changed construction of "slots formed therein" warranted a new trial. D.I. 1295 at 4-6. This ruling, which Cordis did not appeal, is the law of the case and should be adhered to.

BSC also did not waive a new trial by not trying the validity of claim 44 at the second trial in 2005. At that time, both the jury and the Court had already adjudicated claim 44 to be invalid for violating section 305. D.I. 1127 at 51-56; D.I. 182 (C.A. No. 98-197) (Ex. A) at 6. Therefore, the issue of whether claim 44 was invalid over the prior art could not have been tried because there was no live controversy as to the validity of the claim. This issue was moot and not justiciable because claim 44 already stood adjudicated invalid on other grounds under section 305. *See Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1292 (Fed. Cir. 2006) ("In light of this holding [that the claim is invalid under 35 U.S.C. § 112], appellants' remaining [invalidity] arguments concerning the '995 patent are rendered moot."); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1122-23 (Fed. Cir. 2000) (declining to address public use invalidity issue because affirmance of the obviousness decision "moots the remaining issues").

Cordis argues that BSC could have tried the validity of claim 44 at the trial in 2005 because the Court's invalidity decision under section 305 "was an interlocutory ruling and, as such, did not 'adjudicate' anything." Cordis Br. at 26 n.2. According to Cordis, "[p]rior to the entry of judgment on March 27, 2006 (D.I. 1432), BSC had the right to raise an obviousness defense for claim 44 and this Court had jurisdiction to address the issue." *Id.* (citation omitted).

This argument is specious. The jury concluded that claim 44 was invalid under section 305 after a two-week trial in 2000. D.I. 182 (C.A. No. 98-197) (Ex. A) at 6. The Court came to the same conclusion as the jury after it treated the issue as a question for the Court and analyzed it in detail in response to Cordis' post-trial motion. D.I. 1127 at 51-56. The Court's post-trial

decision was a deliberated, final adjudication of the validity of claim 44 after a jury verdict, on which the Court would have entered judgment against Cordis had it not also ordered a new trial on claim 23 and stayed the case against BSC. D.I. 1153 at 9. The fact that the Court did not enter judgment because of the stay did not somehow convert its final decision on the validity of claim 44 into an "interlocutory ruling" that "did not 'adjudicate' anything," as Cordis contends.[13]

Indeed, Cordis agreed before the trial in 2005 that the issue of whether claim 44 is invalid over the prior art should not be tried because the claim was invalid under section 305. BSC moved *in limine* to preclude Cordis from trying validity issues for claim 44 on the ground that these issues were moot and not justiciable, subject, of course, to the outcome of Cordis' appeal:

> [T]he issue of whether claim 44 is obvious will remain moot unless and until Cordis successfully appeals this Court's decision not to set aside the verdict that claim 44 is invalid under 35 U.S.C. § 305. If and when that occurs, depending on the posture of the case at that time, the issue of whether claim 44 is obvious may need to be resolved, but the Court cannot and should not attempt to address that contingency now.

D.I. 1287-5 (Ex. V) at 2. In response, Cordis acknowledged that it "ha[d] not yet had an opportunity to appeal this Court's ruling on claim 44 validity" and agreed that the validity of claim 44 should not be tried, stating that "[i]n Cordis' view, issues involving infringement or validity of claim 44 are outside the scope of this trial" and that "Cordis agrees that the issues for trial do not include the validity of claim 44." D.I. 1299-5 (Ex. W).

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[13] The Supreme Court's statement that "usually . . . the better practice [is to] inquir[e] fully into the validity of [the] patent" does not help Cordis. Cordis Br. at 26. n.2 (quoting *Cardinal Chem. Co. v. Morton Int'l Inc.*, 508 U.S. 83, 100 (1993) (quotation omitted)). The Court made this statement in the context of explaining why a court should address a claim for a declaratory judgment of patent invalidity even if there is no infringement. *See Cardinal*, 508 U.S. at 95-103. It had nothing to do with whether an adjudication that a patent is invalid on one ground renders moot any alternative invalidity grounds.

After not having to defend the validity of claim 44 under the broadened construction of "slots formed therein" at the trial in 2005, Cordis should not be permitted to undo its pretrial concession now. Indeed, if anything, it is Cordis that has waived its waiver argument by agreeing before trial that the issue of whether claim 44 is valid over the prior art was moot and not justiciable at that time.

2. The Broadened Scope of Claim 44 Changes the Comparison of the Claimed Subject Matter to Dr. Carson's Inventive Contribution

The modified construction of "slots formed therein" also warrants a new invalidity trial because the changed construction changes the inventorship analysis by making the claimed subject matter closer to the inventive contribution of an unnamed co-inventor.

There is disputed testimony as to whether Stanley Carson, a vascular surgeon who was Dr. Palmaz's colleague in the early 1980's, was a co-inventor of the subject matter of Dr. Palmaz's patents. Specifically, Dr. Carson testified that he invented the general concept of intraluminally delivering and expanding a stent on a balloon in an artery, and that Dr. Palmaz's contribution was the specific design of the slotted-tube stent. D.I. 202 (C.A. No. 98-197), 12/6/00 Tr. (Ex. BB) at 2286-87, 2291-93, 2297-98.

At the first trial in 2000, the strict construction of "slots formed therein" limited method claim 44 to the use of a stent with openings formed by removing material from a preexisting wall, such as Dr. Palmaz's slotted-tube design of Figures 1A and 1B of the '762 patent.

Under the new construction of "slots formed therein," however, claim 44 has been broadened to include the use of any tubular stent with slots, regardless of how the slots were formed. This broadened claim scope is closer to the general concept of intraluminally delivering and expanding a stent on a balloon in an artery, which Dr. Carson claims to have invented.

Therefore, the changed construction changes the inventorship analysis by changing the comparison of the claim to Dr. Carson's contribution. *See Trovan*, 299 F.3d at 1309 n.2.

This change is not harmless because a jury would not necessarily find that the claimed subject matter was solely invented by Dr. Palmaz under the new construction. *See Ecolab*, 285 F.3d at 1373-74. Moreover, BSC proffered sufficient evidence about Dr. Carson's contribution to support an invalidity verdict under the new construction. D.I. 202 (C.A. No. 98-197), 12/6/00 Tr. (Ex. BB) at 2286-87, 2291-93, 2297-98. A new trial is warranted to permit a jury to compare this evidence to the broadened claim scope to determine if it is invalid for improper inventorship.

III. If Liability Is Found, a New Damages Trial Will Be Required Because Several Important Damages Issues Have Never Been Tried or Have Changed Since the Prior Verdict

Cordis' request for the entry of judgment, an award of prejudgment interest and an accounting of post-verdict sales is premature. Cordis Br. at 35-40. If BSC is found liable for infringement after the liability appeal that is taken from the judgment that will be entered after the new invalidity trial, a new damages trial and further damages proceedings will be necessary because there are a number of damages issues that have never been addressed or that have changed since the prior damages trial in 2000.

A. Several Important Facts Have Changed Since the Damages Trial for Claim 23

If BSC is found liable for infringing claim 23, a new damages trial will be necessary to consider three important issues that have changed since the original damages trial in 2000.

1. The AVE S-Series and Driver Stents Are Now Noninfringing Stents Because of a 2006 Arbitration Decision that They Are Licensed

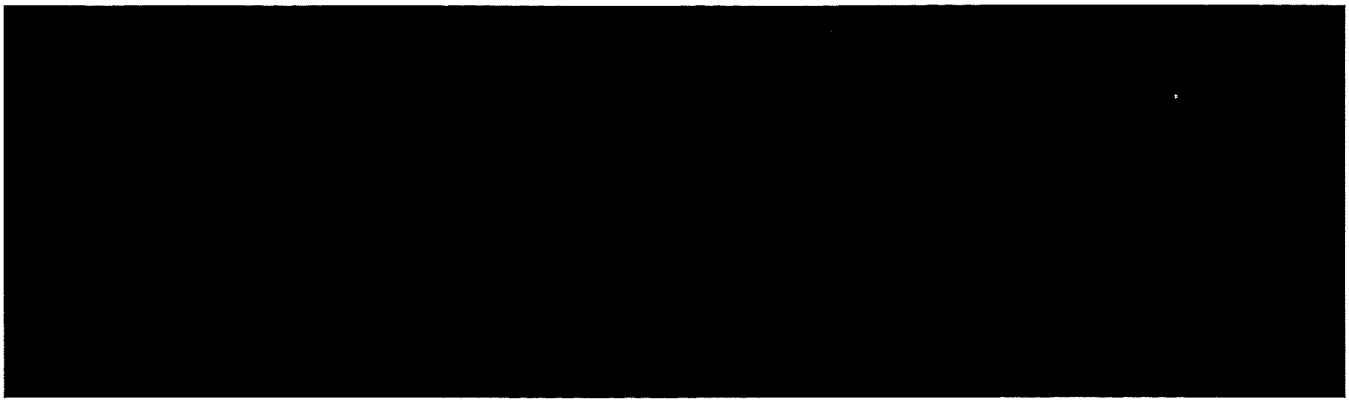
First, a new damages trial is necessary because several AVE stents are now noninfringing stents because of a recent arbitration decision that those stents are licensed under the '762 patent.

At the Cordis-BSC damages trial in 2000, after the verdict that the AVE GFX and Microstent II stents infringed claim 23, Cordis and BSC stipulated (for purposes of the trial only) that the AVE S-Series and Driver stents also infringed.[14] *See* D.I. 205 (C.A. No. 98-197), 12/11/00 Tr. (Ex. CC) at 2838, 2830, 2861; D.I. 1153 at 9. Thus, the jury treated these AVE stents as infringing stents in arriving at its damages verdict against BSC.

After the Court set aside this verdict and granted BSC a new damages trial, an arbitration panel ruled in February 2006 that the AVE S-series and Driver stents are licensed under the '762 patent pursuant to a license agreement between Cordis and AVE's parent company, Medtronic. 2/20/06 Arbitration Decision (Ex. DD); 11/4/97 License Agreement (Ex. EE). Therefore, these AVE stents do not infringe, and Cordis' lost-profits award improperly included NIR stent sales that would have gone to AVE. The damages award at trial did not account for AVE's licensed presence on the market, which would have reduced Cordis' market share and lost profits. *See Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1223 (Fed. Cir. 1995) (limiting lost-profits award to share of infringer's sales that patentee would reasonably have made).

[redacted]

[14] The Court correctly held after the trial in 2000 that BSC did not unconditionally stipulate that the AVE stents, including the S-Series stents, infringe. D.I. 1153 at 9 ("The court finds that BSC did not unconditionally stipulate that the AVE stents infringed the asserted claims of the '762 and '984 patents.").



A new damages trial is necessary to permit a jury to decide these issues for the first time.

2. The ACS Stents Are Now Noninfringing Stents Under the Modified Construction of "Substantially Uniform Thickness"

Second, a new damages trial is also necessary because, as this Court previously held, the issue of whether the ACS stents are noninfringing stents under the new 100% outer limit of the modified construction of "substantially uniform thickness" needs to be tried.

At the damages trial in 2000, BSC argued that the ACS stents did not infringe claim 23 under the prior construction, which limited thickness variations to 0.001 inch, because the protruding struts create variations of 0.0036 inch. D.I. 1127 at 39-42; D.I. 207 (C.A. No. 98-197), 12/13/00 Tr. (Ex. II) at 3326-27. Cordis asserted that the ACS stents literally meet this limitation because the struts are uniformly thick and that they infringe under the doctrine of equivalents because they are functionally equivalent. *See* Cordis Br. at 32; D.I. 206 (C.A. No. 98-197), 12/12/00 Tr. (Ex. GG) at 3210, 3212-18. The jury was not instructed that the range of equivalents was limited and it cannot be determined whether they found infringement literally or by equivalents. D.I. 209 (C.A. No. 98-197), 12/15/00 Tr. (Ex. JJ) at 3887-88; D.I. 203 (C.A. No. 98-197), 12/7/00 Tr. (Ex. KK) at 2750.

In the Cordis-AVE appeal in 2003, the Federal Circuit modified the construction of this term by imposing a new bright line outer limit of 100% to both the literal scope and the range of

equivalents. D.I. 1171 at 17 ("a wall that varies in thickness by as much as 100 percent cannot be said to be of 'substantially uniform thickness' either literally or by equivalents.").

As this Court held in 2006, this changed construction warrants a new damages trial. D.I. 1435 at 5. The changed construction is not harmless because it changed the infringement issue such that the jury would not necessarily have found the ACS stents to infringe under the new construction. *See Ecolab*, 285 F.3d at 1373-74. The jury could have concluded that the ACS stents do not literally meet this limitation under the prior construction because of the thickness variations of 0.0036 inch, but nevertheless concluded that they infringe under the doctrine of equivalents because they are functionally equivalent. Under the new construction, however, the jury would have found no infringement by equivalents as well, because a variation of 0.0036 inch exceeds the 100% outer limit to both the literal scope and the range of equivalents. For example, in an ACS stent with a strut thickness of 0.0025 inch, a thickness variation of 0.0036 is a 144% variation. Since BSC presented sufficient evidence of noninfringement under the new construction, a new trial is warranted. *See Ecolab*, 285 F.3d at 1374-76.[15]

Cordis is wrong when it argues that the prior construction was "narrower" than the new construction because 0.001 inch is equivalent to a thickness variation of only 40% in an ACS stent with a strut thickness of 0.0025 inch. Cordis Br. at 35. Cordis fails to acknowledge that the range of equivalents under the prior construction was unlimited and therefore broader than the new range of equivalents, which is limited to variations of 100%. Thus, when the range of equivalents is taken into account, the new construction is narrower than the prior construction,

[15] The fact that the Federal Circuit concluded that the jury at the trial in 2005 was entitled to conclude that BSC's NIR stent meets the "substantially uniform thickness" limitation under the new construction (Cordis Br. at 33-34) is irrelevant, because the ACS stents are different stents with different features.

and a jury that found infringement by equivalents under the prior construction would not necessarily find infringement under the new construction.[16]

The noninfringing status of the ACS stents will have a significant impact on both lost profits and a reasonable royalty. Cordis' lost-profits award at the trial in 2000 improperly included NIR stents sales that would have gone to ACS, not Cordis. The damages award did not account for ACS's noninfringing presence on the market, which would have reduced Cordis' market share and its lost profits. *See Pall Corp.*, 66 F.3d at 1223. Moreover, the royalty rate to which BSC and Cordis would have agreed in the hypothetical negotiation will also be reduced.

A new trial is warranted to permit a jury to consider these new issues for the first time.

3. A Slightly Modified NIR Stent with Slightly Thicker Welds Would Be a Noninfringing Alternative Under the Modified Construction of "Substantially Uniform Thickness"

Finally, a new damages trial for claim 23 is necessary because the issue of whether BSC could have made and sold a noninfringing NIR stent with slightly thicker welds above the new 100% outer limit of the construction of "substantially uniform thickness" also needs to be tried.

BSC presented undisputed evidence at the liability trial in 2005 that the welds on the actual NIR stent create thickness variations of approximately 74%. *See* D.I. 1372, 3/22/05 Tr. (Ex. L) at 970. BSC should be permitted to present evidence in a new damages trial that it could have manufactured and sold a slightly modified NIR stent with slightly thicker welds above the new 100% outer limit, and that this stent would have been an acceptable, available noninfringing alternative. *See Grain Processing Corp. v. American Maize Prods. Co.*, 185 F.3d 1341, 1354-55

[16] BSC is not precluded by the Cordis-ACS arbitration panel's finding that the ACS stents infringe claim 23 (Cordis Br. 32) because BSC was not a party to the arbitration. *See Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1569 (Fed. Cir. 1993) ("[F]actual findings and legal conclusions in [another case] cannot be used as a collateral estoppel against defendants who were not parties to that case." (citation omitted).

(Fed. Cir. 1999) (a non-infringing alternative was "available" even though it was not made or sold because the accused infringer had the necessary "materials, the equipment, the know-how and experience, and the economic incentive" for the alternative during the infringing period).

The availability of such a modified noninfringing NIR stent would have a significant impact on both the lost profits and reasonable royalty issues. Cordis would not recover any lost profits because BSC would simply have sold the modified noninfringing NIR stent instead. Moreover, BSC would have only paid Cordis a minimal royalty at best, since BSC would otherwise simply have modified the NIR stent to fall outside the scope of the claim.

B. Claim 44 Presents New Damages Issues that Have Never Been Presented or Tried

If BSC is found liable for infringing claim 44 (but not claim 23), a damages trial and further damages proceedings will be necessary. There has never been any damages trial, verdict or other damages proceedings for claim 44, and several damages issues for claim 44 are very different than the damages issues for claim 23, and need to be decided for the first time.[17]

1. Cordis Cannot Recover Damages for Those NIR Stents Which BSC Crimped Outside the United States

A damages trial for claim 44 is necessary because Cordis cannot recover damages for NIR stents crimped on balloon catheters outside the United States. Claim 44 is a method claim that includes the step of "disposing the stent prosthesis upon a catheter having an inflatable balloon portion." '762 Reexam Certificate (Ex. LL), col. 3, ll. 31-32. BSC crimped a significant fraction of the NIR stents that it ultimately sold in the United States on balloon catheters at BSC's facility in Ireland. D.I. 199 (C.A. No. 98-197), 12/1/00 Tr. (Ex. MM) at 1464. Cordis

[17] At the trial in 2000, the jury found that claim 44 was invalid under section 305. D.I. 182 (C.A. No. 98-197) (Ex. A) at 6. Thus, the damages trial in 2000 addressed only damages for claim 23, not claim 44.

cannot recover damages for those NIR stents because claim 44 was not infringed unless every step was performed within the United States. *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005).

BSC should be permitted to present evidence about the number of NIR stents crimped outside the United States to a jury for the first time.[18]

2. Noninfringing NIR Stents Crimped Outside the United States Were Available Noninfringing Alternatives for NIR Stents Crimped Inside the United States

A trial is also necessary because noninfringing NIR stents crimped outside the United States were available noninfringing alternatives for NIR stents crimped inside the United States.

As explained above, NIR stents crimped in Ireland did not infringe claim 44 because one of the claimed steps was not performed within the United States. *NTP*, 418 F.3d at 1318. BSC should be permitted to present evidence to a jury for the first time that it could have switched to this available noninfringing alternative by crimping NIR stents in Ireland.

The availability of such an alternative noninfringing NIR stent will have a significant impact on both the lost profits and reasonable royalty issues. Cordis would not recover any lost profits and BSC would have paid only a minimal royalty, because BSC otherwise would have simply moved all of its crimping offshore.

3. Cordis Cannot Recover Damages for Infringing NIR Stents Sold Prior to the Date of the '762 Reexamination Certificate

In addition to a new trial, the Court should hold that Cordis cannot recover damages for NIR stents sold prior to October 27, 1998, the date the '762 reexamination certificate issued.

[18] Cordis agreed that this issue would need to be addressed in a damages trial for claim 44. D.I. 203 (C.A. No. 98-197), 12/7/00 Tr. (Ex. KK) at 2509 ("This issue . . . will be a damages issue . . . .").

A new claim in a reexamined patent cannot be enforced against activities that occurred prior to the date the reexamination certificate issued unless the claim is "substantially identical" to an original claim in the original patent.[19] 35 U.S.C. § 252, ¶ 1; *see also Bloom Eng'g Co. v. North American Mfg. Co.*, 129 F.3d 1247, 1250 (Fed. Cir. 1997). "[S]ubstantially identical" means "without substantive change." 35 U.S.C. § 252, ¶ 1; *Bloom*, 129 F.3d at 1250 (citation omitted). Such a substantive change exists if the patentee adds a limitation not present in the original claims and relies on that limitation to distinguish newly cited prior art. *See Bloom*, 129 F.3d at 1250-51 (amendment that "narrowed and limited" claims by adding limitation "not included in original claims" to distinguish "newly cited prior art" was "substantive change in claim scope" that barred recovery of damages prior to issuance of reexamination certificate); *see also Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1348-49 (Fed. Cir. 1998).

Cordis should be barred from recovering damages for NIR stents sold prior to October 27, 1998, because it has already conceded that the scope of new claim 44 is substantively different than the scope of the original claims of the '762 patent. Specifically, in support of its cross-appeal that claim 44 is not invalid under section 305, Cordis argued that claim 44 contains several additional limitations not present in original claim 1 on which it relied to distinguish the newly cited prior art during the reexamination. Cordis App. Br. (Ex. M) at 82.

In view of these admitted substantive differences, claim 44 should only have effect from October 27, 1998, and Cordis should not recover any damages for activities prior to that date.

[19] Section 307(b) provides that section 252 of the reissue statute applies to amended or new claims that emerge from reexamination. *See* 35 U.S.C. § 307(b); *id.*, § 252.

4. Cordis' Damages for Claim 44 Are Limited by Intervening Rights

In addition to barring recovery prior to October 27, 1998, the Court should also hold that intervening rights apply to limit Cordis' recovery of damages for NIR stents sold after that date.

"[A]n accused infringer [has] the absolute right to use or sell a product that was made, used, or purchased before the grant of [a reexamination certificate] as long as this activity does not infringe a claim of the [reexamination certificate] that was in the original patent." *BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1220-21 (Fed. Cir. 1993); 35 U.S.C. § 252, ¶ 2. In other words, the accused infringer has "'absolute' intervening rights" to continue to use or sell "products already made at the time" the reexamination certificate issued, such as a product in inventory. *BIC*, 1 F.3d at 1220-21.

An accused infringer may also have "'equitable' intervening rights" which "permit[] the continued manufacture, use, or sale of additional products covered by the [reexamination certificate] when the defendant made, purchased, or used identical products, or made substantial preparations to make, use, or sell identical products, before the [reexamination certificate] date." *Id.* at 1221. "[T]he trial court may, as dictated by the equities, protect investments made before [the reexamination certificate issued]." *Id.*; *Seattle Box Co. v. Indus. Crating & Packing Inc.*, 756 F.2d 1574, 1579-81 (Fed. Cir. 1985); 35 U.S.C. § 252, ¶ 2. Among the factors considered in deciding whether to grant equitable intervening rights is whether the infringer made substantial investments prior to the reexamination proceeding in bringing the infringing product to market. *See, e.g.*, *Richardson-Vicks, Inc. v. The Upjohn Co.*, No. 93-556-SLR, 1996 U.S. Dist. LEXIS 702 (D. Del., Jan. 17, 1996) (Robinson J.), *aff'd*, 122 F.3d 1476 (Fed. Cir. 1997).

The Court should hold that intervening rights apply to limit Cordis' recovery of damages for claim 44. BSC had absolute intervening rights with respect to NIR stents in inventory on or before October 27, 1998. Moreover, the Court should exercise its equitable discretion and find

that BSC has equitable intervening rights with respect to NIR stents made and sold after October 27, 1998, given BSC's substantial investment in bringing the NIR stent to market.

BSC should be permitted to present evidence regarding intervening rights at a later date if and when BSC is found liable for infringing claim 44.

C. Cordis' Arguments About Prejudgment Interest and Post-Verdict Damages Should Be Deferred and Ultimately Rejected

Cordis' request for prejudgment interest and post-verdict damages is premature. The Court should defer any consideration of these issues until if and when it becomes necessary after a new damages trial. BSC respectfully reserves the right to respond to Cordis' arguments about interest and post-verdict damages in more detail at that time. In the meantime, BSC offers the following brief response which identifies some key problems with Cordis' arguments.[20]

1. Prejudgment Interest Should Be Awarded Only on the After-Tax Amount of Damages To Avoid Giving Cordis an Improper Windfall

Although BSC agrees that the base amount of damages (upon which Cordis will have to pay income tax) should be based on the pretax amount of such damages, prejudgment interest should be calculated based only on the after-tax amount of damages, not the pretax amount of damages as Cordis proposes. Cordis Br. at 39-40. Had Cordis received the damages awarded by the jury at the time that the relevant sales of the NIR stent occurred, it would have paid taxes on that income. Thus, for any given quarter, Cordis is not entitled to interest on all of the damages awarded for sales of the NIR stent during that quarter, but only on the after-tax portion of that

[20] Cordis argues that the Court should apply the methodology for calculating post-verdict damages that BSC proposed after the trial in 2000. Cordis Br. at 36-37. Cordis' argument should be rejected because, as explained above, the changed claim constructions and the arbitration decision since then materially affect the determination of both lost profits and a reasonable royalty, and warrant a new damages trial.

award.[21] After paying tax on the entire pretax award, including prejudgment interest on the after-tax damages, Cordis will be put in exactly the same position today that it would have been had it received the pretax amounts due in each year. Cordis' calculation of prejudgment interest based on pretax damages does not account for this factor, but instead provides Cordis with an improper windfall by giving it interest on money Cordis never would have had.[22]

2. Prejudgment Interest Should Be Assessed at the Three-Month T-Bill Rate or at Johnson & Johnson's Actual Cost of Borrowing

Cordis seeks prejudgment interest at the pretax prime rate for the simplistic reason that other cases have used the prime rate on the specific facts of those cases. Cordis Br. 37. However, given the amount at stake and the facts in this case, prejudgment interest should be calculated based on the three-month T-bill rate for the period(s) of time during which Cordis' parent, Johnson & Johnson ("J&J"), did not have to borrow money, and based on J&J's actual cost of borrowing for the period(s) of time, if any, that J&J actually had to borrow money.

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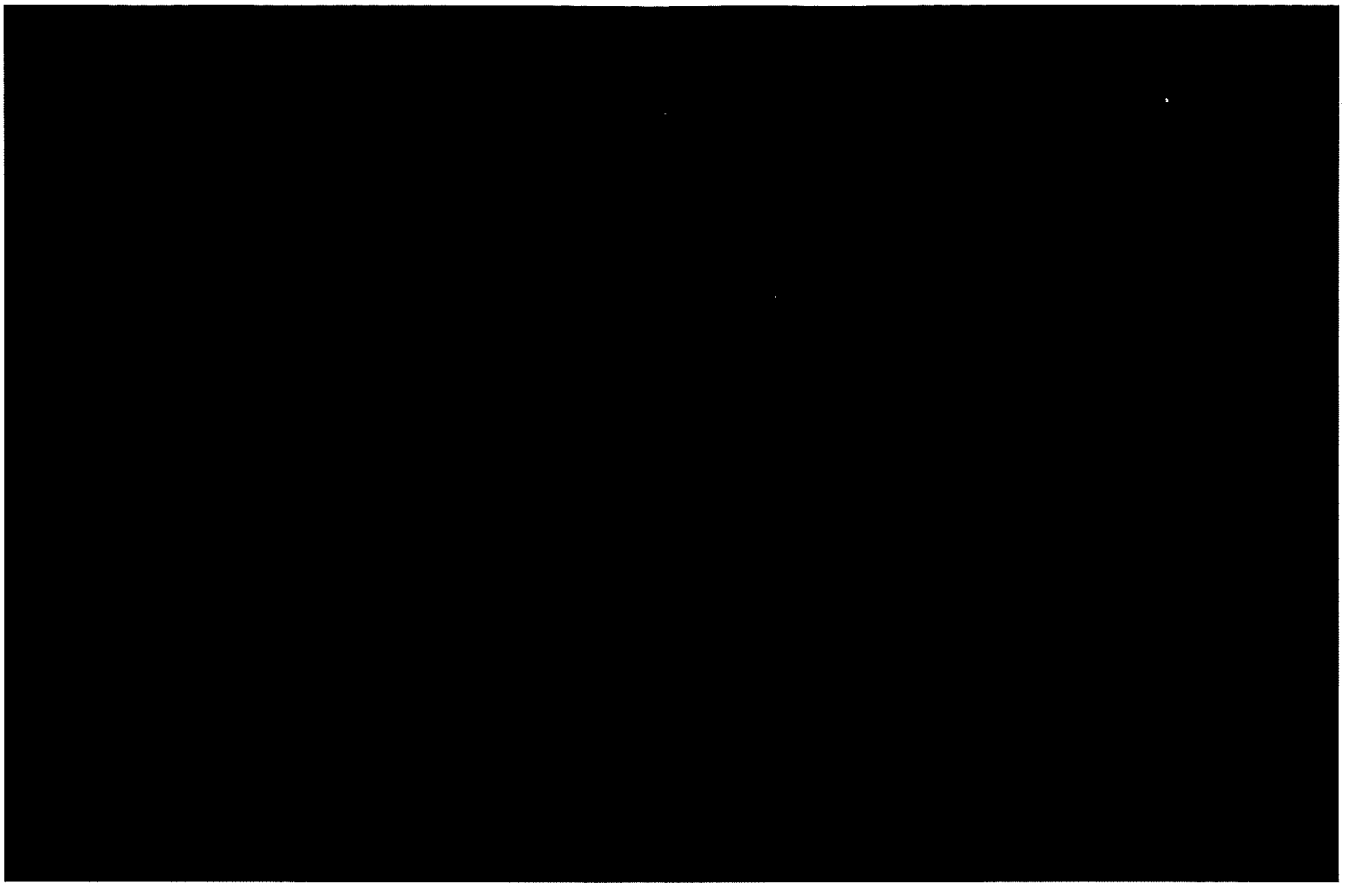
[21] *See Electro Scientific Indus., Inc. v. Gen. Scanning*, 247 F.3d 1341, 1354 (Fed. Cir. 2001) (affirming calculation of prejudgment interest based on after-tax portion of damages award); *Alpex Computer v. Nintendo Co.*, No. 86-1749-KMW, 1994 U.S. Dist. LEXIS 17515, at *176 (S.D.N.Y. Dec. 5, 1994) (calculating prejudgment interest on after-tax basis, stating "[b]ecause Alpex would have had to pay taxes on any profits it earned, it lost the time-value of money on only the after-tax amounts of unpaid royalty payments"), *aff'd in part and rev'd in part on other grounds*, 102 F.3d 1214 (Fed. Cir. 1996).

[22] The cases Cordis cites do not support its argument that prejudgment interest should be calculated based on the pretax amount of damages rather than the after-tax amount of damages. Cordis Br. 39-40. Those cases stand only for the proposition that the base amount of damages should be based on the pretax amount of damages as opposed to the after-tax amount of damages, not that prejudgment interest should be calculated based on the pretax amount of damages as opposed to the after-tax amount of damages. *See Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 503 (1968) (declining to deduct taxes from damages award); *see also Kalman v. Berlyn Corp.*, 914 F.2d 1473, 1482-83 (Fed. Cir. 1990) (same); *see also ATM Express, Inc. v. Montgomery, Ala.*, 516 F. Supp. 2d 1242 (M.D. Ala. 2007) (same). *Hughes Aircraft Co. v. United States*, 86 F.3d 1566 (Fed. Cir. 1996)), is not as close to this case as the decisions cited by BSC because *Hughes* relates to delay compensation in a suit against the United States under 28 U.S.C. § 1498(a). The same distinction holds true for *Standard Mfg. Co. v. United States*, 42 Fed. Cl. 748 (Fed. Cl. 1999) and *Brunswick Corp. v. United States*, 36 Fed. Cl. 204 (Fed. Cl. 1996).



To the extent that J&J was required to borrow money at any time since infringing NIR stent sales began, prejudgment interest for those periods should be calculated based on J&J's actual cost of borrowing. BSC should be permitted at the appropriate time to present evidence showing that this rate was much lower than the prime rate throughout the relevant period.[23] There is no justification for penalizing BSC and overcompensating Cordis and J&J by assessing prejudgment interest at the prime rate when J&J was actually paying a much lower rate.[24]

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[23] *See, e.g., Sun Studs, Inc. v. ATA Equip. Leasing, Inc.*, No. 78-714-RE, 1990 U.S. Dist. LEXIS 18672 (D. Ore. Sept. 19, 1990) (prejudgment interest "calculated based on interest rates *actually charged* plaintiff for short-term borrowing during the applicable periods …" (emphasis in original)).

[24] Cordis' argument that the prime rate should apply in this case because BSC requested the prime rate in C.A. 99-904 (Cordis Br. 37) should be rejected. The fact that BSC requested prejudgment interest at the prime rate on damages for infringement by Cordis' Corinthian stent in that case because BSC's actual cost of borrowing is closer to the prime rate does not mean that the prime rate should be used in this case where J&J's actual cost of borrowing is much lower. If the Court decides to apply the same interest rate

In sum, in a case such as this one where the amount of damages may amount to hundreds of millions of dollars and prejudgment interest rates will make an enormous difference, the parties should be permitted to make careful submissions and present relevant evidence to the Court on this issue if and when that becomes necessary after new validity and damages trials.

* * *

in both cases despite the difference between the parties' actual costs of borrowing, BSC would be willing to accept prejudgment interest based on J&J's actual cost of borrowing in C.A. 99-904.

CONCLUSION

For the reasons set forth above, BSC respectfully requests that the Court deny Cordis' motion for entry of final judgment and grant BSC's cross-motion to defer further proceedings in this case and order a new trial.

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June 10, 2008

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